

Attorney Docket No. 10121/00308 (00-0044CON2)

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE****RECEIVED  
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FEB 20 2007**

Inventor(s) : McAlister et al.  
Serial No. : 10/764,619  
Filing Date : January 26, 2004  
For : Stapling and Cutting in Resectioning for Full Thickness  
Resection Devices  
Group Art Unit : 3734  
Examiner : Michael T. Andersen

Mail Stop: AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

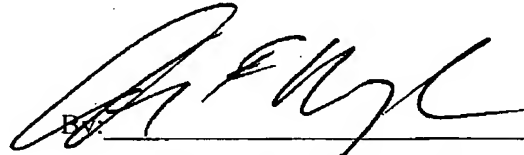
**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Applicants hereby request review of the final rejection in the above-identified application. No amendments are being filed with this Request. This Request is being filed with a Notice of Appeal. The review is requested for the reason(s) stated in the attached Pre-Appeal Brief.

The undersigned is an attorney of record and empowered to sign this Request.

Respectfully submitted,

Dated: February 20, 2007



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**PRE-APPEAL BRIEF**

In support of the Pre-Appeal Brief Request for Review filed herewith, Applicants present a pre-appeal brief in the above-captioned application.

This is a pre-appeal brief regarding the Examiner's final rejection of claims 57 - 72 in the final Office Action dated November 29, 2006 and the Advisory Action of February 1, 2007.

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ARGUMENT

I. The Rejection of Claims 57 - 72 Under 35 U.S.C. § 103(a) as Unpatentable over Mills (U.S. Patent No. 5,037,021) in View of Solar (U.S. Patent No. 5,947,983) Should be Reversed

In the Final Office Action, the Examiner rejected claims 57 - 72 under § 103(a) as unpatentable over Mills in view of Solar. *11/29/06 Office Action*, p. 2. In the Advisory Action, the Examiner maintained that the combination of Mills and Solar discloses a stapling unit consisting of all of the structural elements recited in claims 57 - 72.

Claim 57 recites a stapling unit for an endolumenal stapling system comprising "a housing including a substantially tubular wall and a distal end cap, the housing being slidably coupleable to an endoscope for advancement therealong, the tubular wall including a window extending therethrough with an anvil formed on a first edge of the window, the housing further including *a stapling apparatus mounted within the housing for movement between a stapling position in which a staple firing surface of the stapling apparatus is adjacent to the anvil and a tissue receiving position in which the staple firing surface is separated from the anvil to open the window and expose a tissue receiving cavity within an interior of the housing*, the staple firing apparatus driving a staple out of the staple firing surface through tissue in the tissue receiving cavity" and "a tissue grasping mechanism extendible through the window for drawing tissue through the window into the tissue receiving cavity."

Applicants respectfully submit that the Examiner fails to point to any specific portion of Mills which discloses a stapling unit as claimed. Specifically, a piston 205 does not constitute a staple firing surface "*separated from the anvil to open the window and expose a tissue receiving cavity within an interior of the housing*," as recited in claim 57. The Examiner asserts that a cavity 202 is opened by any movement of the piston 205. That is, Mills provides no suggestion or disclosure whatsoever that movement of the piston 205 opens any window to expose the cavity 202. Mills only states that the piston 205 moves distally to push the tip of the

staple against an anvil 206. *Mills*, col. 6, lines 14-41. There is no indication that the cavity 202 is not already exposed even when the piston 205 is extended to the anvil 205. Thus, it is respectfully submitted that no features of the piston 205 are described which support the suggestion that *Mills* describes a staple firing surface which opens or closes any opening. In addition, the cavity 202 is described only as a tissue receiving space and no window in the housing is described. As recited in claim 57, the staple firing surface opens the window in order to expose a tissue receiving cavity. Thus, the cavity and the window are distinct elements. It is not the cavity itself which opens and closes, but rather a window that provides access to the cavity. Therefore, the cavity 202 cannot be both a tissue receiving cavity and a window. Claim 57 also recites that an anvil is "formed on a first edge of the window." In contrast, *Mills* discloses an anvil 260 located on an inner wall of the cavity separated from the outer edge of the housing where any window would be located. For at least these reasons, it is respectfully submitted that the cavity 202 does not constitute a window which is opened by a staple firing surface to "expose a tissue receiving cavity," as recited in claim 57.

It is respectfully submitted that *Mills* also does not disclose a "staple firing apparatus *driving a staple out of the staple firing surface* through tissue in the tissue receiving cavity," as recited in claim 57. The Examiner reads extra words into the claim to interpret the term "out of" as "out of contact" with or away from. (2/1/07 Advisory Action). The recitation of claim 57 clearly indicates that the staples are initially located within the firing surface and driven out by the stapling apparatus. Interpreting this limitation to mean "out of contact" essentially adds an unnecessary and confusing limitation to an otherwise complete and clear recitation. It is submitted that this is similar to interpreting the phrase "driving a car out of the garage" as including the driving of a car parked outside the garage further away from the garage when it clearly indicates that the car is driven from inside the garage to outside the garage.

For these reasons it is submitted that *Mills* neither shows nor suggests a "staple firing apparatus *driving a staple out of the staple firing surface* through tissue in the tissue receiving cavity," as recited in claim 57 and that claim 57 is allowable. Because claims 58 - 67 depend from and, therefore, include all of the limitations of claim 57, it is respectfully submitted that

these claims are also allowable.

Claim 72 recites limitations substantially similar to claim 57 including “a stapling apparatus mounted within the housing *for movement between a stapling position in which a staple firing surface of the stapling apparatus is adjacent to the anvil and a tissue receiving position in which the staple firing surface is separated from the anvil to open the window and expose a tissue receiving cavity within the housing*, the staple firing apparatus *driving a staple out of the staple firing surface* through tissue in the tissue receiving cavity.” Thus, it is respectfully submitted that claim 72 is allowable for at least the reasons discussed above with regard to claim 57.

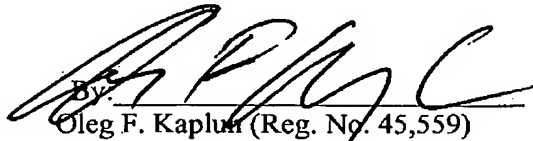
Claim 68 recites a method of endolumenally resecting tissue within a body lumen comprising the steps of “endoscopically locating a portion of tissue to be resected within a body lumen” and “sliding a housing along the endoscope to a desired position adjacent to the portion of tissue to be resected, the housing including a substantially tubular wall and a distal end cap, the tubular wall including a window extending therethrough with an anvil formed on an edge of the window, the housing further including a stapling apparatus movably mounted therewithin, *the stapling apparatus opening and closing the window as it moves within the housing between a tissue receiving position and a stapling position*” in combination with “*moving the stapling apparatus to the tissue receiving position to open the window*” and “drawing the portion of tissue to be resected into the housing through the window folded over so that two full thicknesses of tissue of a wall of the body lumen are received within the window” and “*moving the stapling apparatus to the stapling position clamping the portion of tissue to be resected between the stapling apparatus and the anvil*” in combination with “*driving staples from the stapling apparatus* through the two thicknesses of wall tissue to couple the two thicknesses of wall tissue to one another” and “cutting tissue radially within the stapled tissue from the stapled tissue.”

It is respectfully submitted that claim 68 is allowable based on at least the same reasons discussed above with reference to claim 1. Because claims 69 - 71 depend from and, therefore, include all of the limitations of claim 68, it is respectfully submitted that these claims are also allowable for at least the reasons stated above.

For the reasons set forth above, the Applicants respectfully request that the final rejections of claims 57 - 72 be reversed and that these claims be allowed.

Respectfully submitted,

Dated: February 20, 2007

  
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